

K163537 Arcpoint pulmonary needle - 18 ga, Arcpoint pulmonary needle - 21 ga

Apr 21, 2017
126 days to decision

K163537 · Product code: **EOQ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k163537/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Dec 16, 2016
Decision date	Apr 21, 2017
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	LeeAnne Swiridow
510(k) history	88 submissions · 85 cleared · 2010-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163537/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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